Supreme Court, U.S.
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No. 96-

IN THE
Supreme Court of the United States
OCTOBER TERM, 1996

COLLAGEN CORPORATION,
Petitioner,

v.

ARLENE FIORE, *et al.*,
Respondents.

Petition for Writ of Certiorari to the Arizona Court of Appeals, Division One

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether 21 U.S.C. § 360k(a) preempts common law claims challenging the safety or effectiveness of a medical device that the Food and Drug Administration has found to be safe and effective and has approved for marketing pursuant to the premarket approval process under 21 U.S.C. § 360e(c).*

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* Petitioner Collagen Corporation has no parent corporation and no non-wholly owned subsidiaries.

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PETITION FOR WRIT OF CERTIORARI

Collagen Corporation ("Collagen") respectfully petitions for a writ of certiorari to review the judgment of the Arizona Court of Appeals in this case.

OPINIONS BELOW

The opinion of the Arizona Court of Appeals (App. 1a-17a) is reported at 930 P.2d 477. The opinion of the Superior Court of Maricopa County (App. 18a-20a) is not reported.

JURISDICTION

The judgment of the Arizona Court of Appeals was entered on June 25, 1996. The order of the Supreme Court of Arizona denying Collagen's timely petition for review (App. 21a) was entered on January 14, 1997. This Court's jurisdiction is invoked under 28 U.S.C. § 1257.

STATUTE INVOLVED

21 U.S.C. § 360k(a) in pertinent part provides:

> . . . no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

STATEMENT

A. *Company history and regulatory background.* In the early 1970s, a group of biochemists and physicians at Stanford University developed a purified form of bovine collagen, a natural protein that provides structural support for skin, muscles, tendons, and bones. Together with other investors, they organized respondent Collagen Corporation ("Collagen") to manufacture and distribute collagen products to be used in various medical treatments. The product at issue in this case, Zyderm® Collagen Implant ("Zyderm"), is injected under the skin to correct or improve soft tissue deficiencies that arise from disease, trauma, or aging.

Zyderm is classified by the Food and Drug Administration ("FDA") as a Class III medical device subject to regulation under the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§ 360c-360l. As this Court has noted,

> Before a new Class III device may be introduced to the market, the manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. See 21 U.S.C. § 360e(d)(2). Despite its relatively innocuous phrasing, the process of establishing this "reasonable assurance," which is

known as the "premarket approval," or "PMA" process, is a rigorous one.

Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2246-47 (1996).

The PMA process entails an exhaustive investigation into safety and effectiveness with respect to (1) the persons for whose use the device is intended and (2) the conditions of use prescribed, recommended, or suggested in the labeling of the device. 21 U.S.C. § 360c(2). An applicant who seeks the FDA's approval to market a Class III device must provide:

> (A) full reports of all information, published or known to . . . the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;
>
> (B) a full statement of the components, ingredients, and properties and of the principle or principles of operation of, such device;
>
> (C) a full description of the methods used in, and the facilities and controls used for, the manufacture [and] processing . . . of such device;
>
> (D) . . . adequate information to show that . . . such device fully meets [pertinent] performance standard[s] . . .;
>
> (E) . . . samples of such device . . .;
>
> (F) specimens of the labeling proposed to be used for such device; and
>
> (G) such other information . . . as the [FDA] . . . may require.

21 U.S.C. § 360e(c)(1).

The application for premarket approval also must include, *inter alia*, a "general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended," an "explanation of how

the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device," and a "description of existing alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended." 21 C.F.R. § 814.20(b)(3). The application must be periodically updated "with new safety and effectiveness information learned about the device from ongoing or completed studies." 21 C.F.R. § 814.20(e).

A completed application is reviewed by a panel of experts. 21 U.S.C. § 360e(c)(2). After considering the panel's report and recommendation, the FDA will grant the application only if it finds reasonable assurance (1) that the device is safe and effective with respect to both the persons for whose use the device is intended and the conditions of use prescribed, recommended, or suggested in its labeling, (2) that the manufacturing and processing methods and facilities are satisfactory, and (3) that the proposed labeling is not false or misleading in any manner. 21 U.S.C. §§ 360c(2) and 360e(d)(2); *see also* 21 C.F.R. § 814.44.

Collagen filed an application with the FDA for premarket approval of Zyderm on April 30, 1980. Its application included, *inter alia*, the results of clinical testing in over five thousand human subjects. Pet. Rev. App. 3 ("Pet. Rev. App." refers to the appendix for the petition for review in the Supreme Court of Arizona). Following more than one year of detailed investigation, the FDA found Zyderm to be safe and effective and approved it for marketing. 46 Fed. Reg. 46394 (1981). The FDA's approval order for Zyderm set forth numerous "conditions of approval," including the following:

> *Before making any change that may affect the safety or effectiveness* of the device, [Collagen must] submit a supplemental PMA for review and approval by FDA. Such changes include, but are not limited to:

(1) new indications for use;

(2) labeling changes;

(3) changes in manufacturing facilities, methods or quality control procedures, and involvement of new subcontractors, suppliers, or distributors;

(4) changes in sterilization procedures;

(5) changes in packaging;

(6) changes in the performance or design specifications, circuits parts, components, accessories, ingredients, or physical layout of the device.

Pet. Rev. App. 6. Since 1981, Collagen has marketed Zyderm as a prescription-only medical device pursuant to the authority granted by the FDA in this approval order. In 1991, the FDA reviewed Zyderm's record and reconfirmed its initial finding of safety and effectiveness. Pet. Rev. App. 1, ¶ 7.

B. *Proceedings in this case.* Respondent Arlene Fiore was treated with Zyderm during or before 1987. App. 4a. In February 1993, she and her husband sued Collagen in the Superior Court of Maricopa County, Arizona, alleging that the treatment had caused her "serious physical and emotional injury." *Id.* The complaint asserted claims against Collagen

> (1) for negligence in developing, testing, manufacturing, inspecting, labeling, marketing, promoting, advertising, selling and distributing Zyderm; (2) for strict liability; (3) for breach of express and implied warranties that Zyderm was safe, fit, and proper for cosmetic use; and (4) for negligent or fraudulent representations of Zyderm's safety and fitness to Fiore, her physicians, the FDA, and the general public.

Id. at 5a.

Collagen moved for summary judgment on the ground that respondents' tort claims were barred by the MDA preemption statute, 21 U.S.C. § 360k(a). That statute bars states from imposing, with respect to a medical device,

"any requirement—(1) which is different from, or in addition to, any requirement applicable under [the MDA] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the MDA]." The trial court granted Collagen's motion, holding that respondents' claims were barred for the reasons stated in *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993), and *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993). App. 19a-20a.

The Arizona Court of Appeals reversed and remanded for further proceedings. App. 17a. The court acknowledged that the overwhelming majority of courts to have considered the issue had concluded that section 360k(a) fully or partially preempts state common law claims against manufacturers of medical devices. *See id.* at 8a & n.4 (citing cases from the First, Third, Fourth, Fifth, Sixth, Seventh, Eighth, and Eleventh Circuits as well as from Oregon, California, and Pennsylvania). The court noted, however, that in *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995), *cert. denied*, 116 S. Ct. 2579 (1996), the Ninth Circuit had held, to the contrary, that state common law does not impose "requirements" within the meaning of section 360k(a) and thus is not preempted. *Id.* at 10a-12a. The court "adopt[ed] *Kennedy* as the better reasoned view of preemption, despite its distinct minority status." *Id.* at 13a. The court also was persuaded that "[t]he *Kennedy* approach provides the additional advantage that identical rules apply in Arizona's state and federal courts." *Id.*

The Supreme Court of Arizona denied Collagen's timely petition for review. App. 21a.

REASONS FOR GRANTING THE PETITION

The decision below conflicts with the post-*Lohr* decision in *Green v. Dolsky*, 685 A.2d 110 (1996), *pets. for cert. pending* (Nos. 96-1340 & 96-1451), and raises precisely the same issue under 21 U.S.C. § 360k(a). For the reasons stated by Collagen in its submissions to this Court in *Green*, review should be granted to resolve the conflict and decide the important and recurring question of federal preemption that these cases present.

It should be noted, moreover, that *Lohr* undermines the rationale of the decision below. This Court in *Lohr* considered the application of section 360k(a) to medical devices that, unlike Zyderm, have not "run[] the gauntlet of the PMA process." *Lohr*, 116 S. Ct. at 2254. The Court held that, in that context, state common law claims are not preempted because the federal requirements imposed with respect to such devices are too nebulous to give rise to preemption. *Id.* at 2253-55, 2256-58. A majority of Justices, however, made clear that state common law does impose "requirements" within the meaning of section 360k(a) and thus, in a proper case, may be subject to preemption. *Id.* at 2262-63 (O'Connor, J., concurring and dissenting) ("the term 'requirement' encompasses state common-law causes of action"); *id.* at 2259-60 (Breyer, J., concurring) ("the MDA will sometimes preempt a state-law tort suit"). This majority determination in *Lohr* expressly contradicts the premise on which the decision below was based.

The lower court's mistaken premise—that "the MDA does not preempt state common law tort claims," App. 2a—was borrowed from the Ninth Circuit's earlier decision in *Kennedy*. After this Court's decision in *Lohr*, the Ninth Circuit recanted, correctly acknowledging that its reasoning in *Kennedy* had been mistaken. *Papike v. Tambrands Inc.*, No. 95-55173, 1997 WL 74348, at *7 (9th Cir. Feb. 20, 1997) (*Kennedy's* "conclusion that a common-law claim cannot be preempted does not

survive the five Justices' contrary conclusion in [*Lohr*]"). The decision below now stands virtually alone in its incorrect construction and application of section 360k(a).

Accordingly, this petition and those in *Green* should be granted. However, if the Court does not wish to address the merits of the question presented here and in *Green* at this time, and thus declines to grant the petition and cross-petition in *Green*, it nevertheless would be appropriate for the Court to grant this petition, vacate the judgment below, and remand for reconsideration in light of *Lohr* and *Papike*.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDICES

APPENDIX A

[Filed Jun. 25, 1996]

IN THE COURT OF APPEALS
STATE OF ARIZONA
DIVISION ONE

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1 CA-CV 94-0375
Department A

ARLENE FIORE and RICHARD FIORE,
Plaintiffs-Appellants,

v.

COLLAGEN CORPORATION,
a Delaware corporation,
Defendant-Appellee.

Appeal from the Superior Court of Maricopa County

Cause No. CV 93-02661

The Honorable Barbara M. Jarrett, Judge
The Honorable Cheryl K. Hendrix, Judge

REVERSED AND REMANDED

OPINION

TOCI, Judge

Plaintiffs Arlene and Richard Fiore ("Fiore") appeal from the summary judgment granted to Collagen Corporation ("Collagen Corporation") in Fiore's products

liability action. Fiore sued Collagen Corporation for Arlene's injuries after she received injections of Zyderm Collagen Implant ("Zyderm"), an anti-wrinkle susbstance manufactured and sold by Collagen Corporation.

The trial court found that a section of the Medical Device Amendments of 1976 ("MDA") preempted Fiore's claims for negligence, strict liability in tort, breach of express and implied warranty, and fraud. It also denied leave to file an amended complaint alleging a violation of the Arizona Consumer Fraud Act after the court had granted summary judgment on the original complaint. We conclude that the MDA does not preempt state common law tort claims and thus reverse the judgment and remand for further proceedings consistent with this opinion. Therefore, we need not resolve whether the trial court erred in denying the motion to file an amended complaint.

I. FACTUAL AND PROCEDURAL BACKGROUND

Collagen Corporation manufactures and distributes products made from a purified form of bovine collagen. One of these products, Zyderm, is injected under the skin to correct or improve soft tissue deficiencies due to disease, trauma, or age. Zyderm is considered a Class III medical device.

Prior to 1976, the United States Food and Drug Administration ("FDA") lacked authority to examine the safety and effectiveness of any medical device before the maker sold the device to the public unless the FDA could convince a court that the device was a drug. Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 910-11 (1994) ("Adler & Mann"). As a consequence of the Dalkon Shield litigation, Congress amended the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-93 (1972), to extend the FDA's jurisdiction to medical devices. Adler & Mann, *supra*, at 911-12 n.84; *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1319 (3d Cir.), *cert. denied*,

116 S. Ct. 67 (1995). These amendments, codified at 21 U.S.C. §§ 360c through 360*l* (Supp. 1995), are referred to as the Medical Device Amendments of 1976 or "MDA".

Pursuant to these statutes, the FDA classifies all medical devices. The categories and the corresponding legal consequences of each can be briefly described as follows:

> Class I devices, such as tongue depressors, are devices which generally pose little or no threat to public health and are subject only to general controls on manufacturing. *See* 21 U.S.C. § 360c(a)(1)(A). Class II devices, such as oxygen masks, pose a slightly greater risk of injury to patients, and accordingly, the MDA subjects them to performance standards, post market surveillance, guidelines for use and other appropriate controls. *See id.* § 360c(a)(1)(B). Class III devices . . . include all devices which are to be implanted into people, which are used to sustain life, or which pose a potentially unreasonable risk of injury. *See id.* § 360c(a)(1)(C).

Michael, 46 F.3d at 1319-20.

Under the MDA, no company may market or sell a Class III device until it obtains premarket approval from the FDA. 21 U.S.C. § 360e. The sponsoring company must submit "all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective," 21 U.S.C. § 360e(c)(1)(A), a description of the product's ingredients, method of manufacture, and performance standards, as well as any other information requested by the FDA, 21 U.S.C. § 360e(c)(1)(B)-(G). Following review by a panel of medical experts and a favorable recommendation, the FDA may approve the application.

Additionally, the FDA's regulations permit it to require warnings or instructions on the product's labels and to regulate the manufacturing processes. 21 C.F.R. § 814.82,

820.100-101. The FDA may require the product's sponsor to notify the public of a newly-discovered danger, to replace the device, or to refund its purchase price. 21 U.S.C. § 360h. The FDA's continuing authority also requires manufacturers to report deaths or serious injuries from use of a Class III device. *See* 21 C.F.R. § 803.24 (a)(i). The Act does not, however, authorize the FDA to require companies to compensate victims for either medical expenses or pain and suffering caused by a device failure. *See Mears v. Marshall,* 905 P.2d 1154, 1160 (Or. App. 1995) (no private right of action).

On April 30, 1980, Collagen Corporation filed a premarket approval application for Zyderm. A panel of experts reviewed the application and imposed a number of conditions on Collagen Corporation.[1] In July 1981, the FDA issued an order permitting Collagen Corporation to market Zyderm. In 1991 and 1992, the FDA reviewed the premarket approval application and concluded that its initial approval of the application was appropriate.

In 1986 or 1987, Arlene Fiore received Zyderm injections. She filed this products liability action against Collagen Corporation and her doctor in February 1993, alleging that Collagen Corporation knew or should have known that the human immune system views Zyderm as a foreign protein, and thus Zyderm provokes significant immune and autoimmune reactions. The complaint stated that after the injections, Arlene suffered serious physical and emotional injury and was diagnosed with an autoimmune disease and other related conditions. The com-

[1] The FDA required Collagen Corporation to obtain its approval of any change that might adversely affect Zyderm's safety or effectiveness; to submit copies of all labeling in final printed form; to conduct studies of treated patients; to promptly report adverse reactions or incidents of mislabeling or failure to meet the PMA specifications; and to submit all written promotional materials, annual reports, including reports of *in vitro,* animal, and clinical studies, and descriptions of any changes in Zyderm not previously submitted in a supplemental premarket approval application.

plaint alleged claims against Collagen Corporation (1) for negligence in developing, testing, manufacturing, inspecting, labeling, marketing, promoting, advertising, selling and distributing Zyderm; (2) for strict liability; (3) for breach of express and implied warranties that Zyderm was safe, fit, and proper for cosmetic use; and (4) for negligent or fraudulent representations of Zyderm's safety and fitness to Fiore, her physicians, the FDA, and the general public.

Collagen Corporation successfully moved for summary judgment on the theory that 21 U.S.C. §§ 360c through 360ss and the FDA regulations preempted all of Fiore's claims.[2] Fiore then moved for leave to file an amended complaint alleging a claim against Collagen Corporation for violation of the Arizona Consumer Fraud Act, A.R.S. sections 44-1521 through -1534 (1994). The trial court denied the motion as untimely. We have appellate jurisdiction pursuant to A.R.S. section 12-2101(B) (1994).

II. DISCUSSION

A. Standard of Review

We review *de novo* the trial court's interpretation of a statute. *Chaffi v. Commissioner of the Ariz. Dep't of Real Estate*, 164 Ariz. 474, 476, 793 P.2d 1141, 1143 (App. 1990). In reviewing the trial court's grant of

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[2] The trial court cited two recent federal cases finding preemption under the MDA and relevant regulations, *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993) (defective design, inadequate warning, and negligent failure to warn), and *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993) (strict liability, breach of express and implied warranties, negligent design, manufacturing and sale, misbranding, and failure to warn claims preempted by the MDA). As a matter of comity, the court gave substantial weight to the two decisions and found no valid authority to hold that they were wrongly decided. Therefore, the court adopted the views of the Fifth and First Circuits and found Fiore's claims preempted by federal law.

summary judgment, we view the evidence and all reasonable inferences in the light most favorable to the nonmoving party. *Hill v. Chubb Life Am. Ins. Co.*, 182 Ariz. 158, 160, 894 P.2d 701, 703 (1995).

B. Federal Preemption Doctrine in the Context of Cigarette Regulation

The preemption doctrine derives from the Supremacy Clause of the Constitution, which states: "This Constitution, and the Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. Art. VI, Cl. 2. Thus, federal laws or regulations supersede conflicting state laws. *See Hillsborough County v. Automated Medical Lab., Inc.*, 471 U.S. 707, 713 (1985).

Numerous federal circuit and district courts have relied upon the preemption doctrine to eliminate or restrict state common law causes of action against manufacturers of medical devices. Many of these decisions adopted the reasoning of the United States Supreme Court in *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992). *Cipollone* held that federal statutes regulating cigarette advertising and labeling evidenced a congressional intent to preempt at least some state tort claims. *Id.* at 2618. The Court thus found precluded some causes of action based on Cipollone's death from lung cancer. *Id.* at 2621.

Federal law does not supersede state regulation, however, "unless that [is] the clear and manifest purpose of Congress." *Id.* at 2617 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Further, "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted." *Id.* at 2618.[3]

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[3] The Court later stated that while *Cipollone* did not establish a rule that an express preemption clause entirely forecloses implied

In *Cipollone*, the Court "narrowly" construed the language of the 1965 Act regulating cigarette labeling and advertising "in light of the presumption against the pre-emption of state police power regulation." *Id.* The 1965 Act expressly provided for preemption and stated in part, "No statement relating to smoking and health, other than the statement required by section 4 of this Act, shall be required on any cigarette package." It also provided, "No statement relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labelled in conformity with . . . this Act." § 5(a), (b). The Court noted that the federally required warning on cigarettes did not automatically "foreclose additional [state-imposed] obligations," and it found no "inherent conflict between federal pre-emption of state warning requirements and the continued vitality of state common law damages actions." *Id.* Thus, the statute superseded only positive state enactments "that mandate particular warning labels . . . but not common law damages actions." *Id.* at 2618-19.

The Court reached a different conclusion in analyzing the 1969 Public Health Cigarette Smoking Act. The statute's express preemption provision read: "(b) No *requirement or prohibition* based on smoking and health *shall be imposed under State law* with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." *Id.* at 2617 (emphasis added). This more sweeping language extended beyond the word "state ments" used in the 1965 Act to bar state-imposed "requirement[s] or prohibition[s]." *Id.* at 2619. The Court found the latter terms to include not only state statutes or "positive enactments" but also common law damages actions premised on payment of compensation for breach of a legal duty. *Id.* at 2620.

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preemption, an express clause nevertheless implies such an effect. *Freightliner Corp. v. Myrick*, 115 S. Ct. 1483, 1487-88 (1995).

The Court then analyzed each common law claim to determine if it constituted a "requirement or prohibition based on smoking and health . . . imposed under State law with respect to . . . advertising or promotion . . . ." *Id.* at 2621. It found preemption of claims for failure to warn but not of claims for express warranty, intentional fraud and misrepresentation, or conspiracy to misrepresent or conceal. *Id.* at 2621-25.

C. Preemption Under the MDA

As with the cigarette legislation, the MDA contains an express preemption provision. It states:

> Except as provided in subsection (b) . . . , no State . . . may establish or continue in effect with respect to a device intended for human use any *requirement*—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device . . . .

21 U.S.C. § 360k(a) (emphasis added).

A majority of post-*Cipollone* decisions interpreting § 360k(a) concludes that Congress intended "requirement" to include state common law tort claims of general application and thus find full or partial preemption of such claims against manufacturers of medical devices.[4]

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[4] *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995) (all state law product liability and breach of warranty claims preempted); *Mendes v. Medtronic, Inc.*, 18 F.3d 13 (1st Cir. 1994) (negligence and breach of warranty claims based on failure to warn and manufacturing defect preempted); *King v. Collagen Corp.*, 983 F.2d 1130 (strict liability, implied warranty of merchantability, negligent design, manufacture, marketing and sale, misbranding or mislabeling, failure to warn, and express warranty claims preempted); *English v. Mentor Corp.*, 67 F.3d 477 (3d Cir. 1995)

Mitchell v. Collagen Corp., 67 F.3d 1268 (7th Cir. 1995), exemplifies this view.

(all state law claims preempted except express warranty); *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994) (product liability and negligence claims preempted); *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392 (4th Cir. 1995) (all state claims preempted other than express warranty claim unrelated to FDA-approved labeling and warnings); *Feldt v. Mentor Corp.*, 61 F.3d 431 (5th Cir. 1995) (failure to warn claims preempted; design defect claims on non-PMA Class III device not preempted); *Reeves v. Acromed Corp.*, 44 F.3d 300 (5th Cir.), *cert. denied*, 115 S. Ct. 2251 (1995) (failure to warn claim preempted; strict liability claim based on off-label use of Class III medical device not preempted); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (defective design, inadequate warning and negligent failure to warn claims preempted); *Martin v. Telectronics Pacing Systems, Inc.*, 70 F.3d 39 (6th Cir. 1995) (all state law product liability and breach of warranty claims preempted); *Mitchell v. Collagen Corp.*, 67 F.3d 1268 (7th Cir. 1995) (fraud on FDA, strict liability, negligence, mislabeling, packaging and labeling fraud, implied warranty claims preempted; fraud in advertising and promotion materials and express warrantly claims not preempted); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 506 U.S. 917 (1992) (all product liability claims preempted; limited to efforts by states to impose sanctions for federal regulations relating to safety of experimental lenses); *Martello v. Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995) (strict liability; branch of express and implied warranty; and negligent design, inspection, instructions, labeling, warning, and testing claims preempted); *National Bank of Commerce of El Dorado v. Kimberly-Clark Corp.*, 38 F.2d 988 (8th Cir. 1994) (negligent labeling claim preempted because approved by FDA; negligent testing, design, and manufacture claims on Class II device not preempted); *Lohr v. Medtronic, Inc.*, 56 F.3d 1335 (11th Cir. 1995), *cert. granted*, 116 S. Ct. 806 (1996) (negligent manufacture and negligent failure to warn claims preempted; negligent design and strict liability claims not preempted on non-PMA Class III device); *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994) (negligence, strict liability and breach of implied warranty claims preempted); *Blanchard v. Collagen Corp.*, 909 F. Supp. 427 (E.D. La. 1995) (strict liability and negligence in failure to warn, design and manufacture preempted; strict liability and negligence based on contamination not preempted where manufacture not in accordance with FDA standards); *Evraets v. Inter-*

In *Mitchell*, the Seventh Circuit Court of Appeals relied upon *Cipollone*'s holding that the 1969 Act's phrase, "No requirement or prohibition . . . shall be imposed under State law," included state common law rules. 67 F.3d at 1275-76. Therefore, the Seventh Circuit concluded that § 360k(a)'s preemption of state requirements "different from, or in addition to," those of the MDA included state common law causes of action. The court cited an FDA regulation interpreting the statute to preempt state requirements establishing by "statute, ordinance, regulation, or court decision," 21 C.F.R. § 808.1(b), as further evidence of preemption of state common law claims. 67 F.3d at 1275-76.

The Ninth Circuit Court of Appeals in November 1995 rejected this view in *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995). The plaintiff, who had developed an autoimmune disorder after receiving Zyderm injections, and her husband asserted claims for negligence, strict liability, breach of warranty, battery, conspiracy, and loss of consortium. *Id.* at 1454. The district court granted summary judgment for Collagen Corporation on preemption grounds after finding that the premarket approval process constitutes a specific federal requirement that preempts state common law claims. *Id.* at 1458.

The Ninth Circuit reversed and held that generally applicable state common law, including tort law, is not

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medics Intraocular, Inc., 34 Cal. Rptr. 2d 852 (App. 1994) (negligence and strict liability claims preempted; express warranty, fraud, and negligence per se claims not preempted); *Mears v. Marshall*, 905 U.2d 1154 (strict liability, implied warranty, express warranty based on brochures and packaging approved by FDA, and negligence claims preempted); *Rosci v. Acromed, Inc.*, 669 A.2d 959 (Pa. Super. 1995) (implied warranty claims preempted; express warranty claims not preempted); *Green v. Dolsky*, 433 Pa. Super. 556, 641 A.2d 600 (1994) (mislabeling, misbranding, adulteration, fraud, misrepresentation and breach of warranty claims preempted). *Contra Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995).

preempted by § 360k(a). *Id.* at 1459-60. Under 21 U.S.C. § 360k(a)(1), a preempted state "requirement" is one that is either "in addition to" or "different from" an MDA requirement applicable to the device in question. Because Congress had not addressed the question of what constitutes a "State requirement" under § 360k(a), the court looked to the FDA's own interpretation expressed in its regulation, 21 C.F.R. section 808.1(d). 67 F.3d at 1457-58.

Section 808.1(d) provides that state requirements are preempted "*only* when the Food and Drug Administration has established *specific* counterpart regulations or . . . other *specific* requirements appl[y] to a *particular device* under . . . the act, thereby making any existing divergent State . . . requirements applicable to the device different from or in addition to, the *specific* Food and Drug Administration requirements." (Emphasis added.) The Ninth Circuit noted that the courts have not often found common law tort actions involving Class II devices preempted and questioned the failure to comparably construe the words "particular device" when dealing with Class III devices. 67 F.3d at 1458. Further, the fact that the premarket approval process entailed compliance with a number of mandatory procedures specific to the device in question did not necessarily mean that the premarket approval process itself was a "specific requirement applicable to a particular device under the act" within 21 C.F.R. § 808.1(d). 67 F.3d at 1459.

The court also noted that 21 U.S.C. § 360k(a) "does not preempt State . . . requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices . . . or to unfair trade practices . . . ." *Id.* at 1457-58 (quoting 21 C.F.R. § 808.1(d)); *see, e.g.*, § 808.1(d)(1) and (6)(ii). Because "state common law does not relate solely to or regulate any *particular* device or product to the exclusion of other devices or products," it is not preempted. 67 F.3d at 1459. Furthermore, although the court acknowledged,

as the Supreme Court had in *Cipollone*, that the common law may have an indirect regulatory effect on manufacturers, it found the effect "insufficient to alter the fact that state common law is a law of general applicability and therefore cannot qualify as a *specific* requirement which may be preempted by the MDA." *Id.*

Finally, the court could not accept the consequence of a finding of preemption. "[I]t is incredible to believe that Congress would, without comment, void all means of relief for those injured by illegal conduct." *Id.* (citing *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)). To read the MDA preemption to preclude any and all remedies in state or federal court "flies in the face of the congressional intent behind the MDA legislation: consumer protection." *Id.; see also* Adler & Mann, *supra*, at 922-23 n.126 (the MDA legislative history reveals "critical, and endlessly repeated focus" on protecting consumers from dangerous devices).

Judge Reinhardt's concurring opinion in *Kennedy* further explained the meaning of "State requirement." He noted that decisions such as *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994), relied upon the FDA's reference to "court decisions" in 21 C.F.R. § 808.1(b)[5] to find preemption

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[5] Section 808.1(b) provides:

> Section 521(a) of the act [21 U.S.C. § 360k(a)] contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (*whether established by statute, ordinance, regulation, or court decision*), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act. (Emphasis added).

of state tort claims. Judge Reinhardt concluded, however, that despite the reference to court decisions in section 808.1(b), "Section 808.1(d)(1) specifically provides that 'requirements' involving laws of general applicability, are not preempted. Since under § 808.1(b), 'requirements' includes 'court decisions,' 'court decisions' must be read as not including decisions involving rules of general applicability." 67 F.3d at 1461-62. Thus the reference to "court decision" in section 808.1(b) could not modify section 808.1(d), which limits "requirements" to provisions applicable expressly to medical devices. *Id.*

We adopt *Kennedy* as the better reasoned view of preemption, despite its distinct minority status. In addition, "We customarily find Ninth Circuit authority persuasive on a federal question." *State v. Burkett*, 179 Ariz. 109, 112, 876 P.2d 1144, 1147 (App. 1993), *cert. denied*, 115 S. Ct. 923 (1995). The *Kennedy* approach provides the additional advantage that identical rules apply in Arizona's state and federal courts. *See State v. Maese*, 27 Ariz. App. 379, 381, 555 P.2d 348, 350 (1976) (Ninth Circuit rule controls; defendant would receive same result in federal court review of sentence). We cannot accept the suggestion that without serious study or debate on this question Congress would eliminate common law remedies available to persons injured by medical devices.

If a primary purpose of MDA were safety,

> it would be strange for Congress to eliminate the safety aspects inherent in tort litigation by destroying tort litigation . . . with the same statute it passed to promote safety. It would be stranger still . . . to take such a dramatic action without even mentioning it as a consequence of the passage of a bill that was debated for years. Yet the debate and Congressional record are barren of any indication that Congress intended to preempt court decisions by passing the 1976 Medical Device Amendments.

Haudrich v. Howmedica, Inc., 642 N.E.2d 206, 211-12 (Ill. App. 1994) (citations omitted).[6]

The thoughtful analysis of Justice Chapman in *Haudrich* buttresses a narrow reading of 21 U.S.C. § 360k.[7] From a careful consideration of the entire statute, Justice Chapman found, for example, that Congress did not intend "State or political subdivision" to include state courts and thus that courts cannot be the source of "requirements" that are preempted. 642 N.E.2d at 210. To interpret "State" to include state courts would plainly include political subdivisions of the state. Because § 360k

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[6] The Illinois Supreme Court determined that the defendant in *Haudrich* had waived the preemption issue in the trial court, and therefore declined to reach it.

[7] 21 U.S.C. § 360k states:

> (a) General rule
>
> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.
>
> (b) Exempt requirements
>
> Upon application of a State or a political subdivision thereof, the Secretary may, by regulation . . ., exempt from subsection (a) . . ., under [prescribed] conditions . . ., a requirement of such State or political subdivision applicable to a device intended for human use if—
>
> (1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or
>
> (2) the requirement—
>
> (A) is required by compelling local conditions, and
>
> (B) compliance with the requirement could not cause the device to be in violation of any applicable requirement under this chapter.

expressly includes "political subdivision" as an entity distinct from the "State," however, the term "State" must be given its ordinary meaning in order to give independent meaning to the term "political subdivision." *Id.*

Justice Chapman inferred, from repeated use of the word "requirement" to designate legislative or regulatory actions of both Congress and the FDA and also to refer to actions of "States or political subdivisions," that "requirement" means legislative or regulatory acts rather than adjudicatory acts of the courts. *See id.* at 210-11; *see also* Adler & Mann, *supra*, at 827-28. Further, he found, from the reference to "establish or continue in effect a requirement," an intent to cover requirements imposed by statute or regulation as opposed to case law because the latter "is handed down, developed, or decreed." 642 N.E.2d at 210. Similarly, he concluded from the provision permitting the Secretary to exempt a requirement of a State or political subdivision that the Secretary would not normally exempt a court decision. Thus, the exemption power likely exists over statutes, ordinances, or regulations. *Id.*

Also, in our opinion, the Committee Report on the MDA supports this inference. It expressed concern that differing requirements imposed by *jurisdictions* other than the Federal government would unduly burden interstate commerce. The new section 521 "contains special provisions . . . governing regulation of devices by *States and localities*." 642 N.E.2d at 210 (emphasis added) (quoting D. O'Keefe & R. Spiegel, *An Analytical Legislative History of the Medical Device Amendments of 1976*, App. III, at 45 (1976)). The Report cited California's 1970 Sherman Food, Drug, and Cosmetic Law as an example of a "requirement" that should be exempted from preemption. *Id.* at 212 (quoting O'Keefe & Spiegel, *supra*, App. III at 46). It did not mention any case law or court decisions. 642 N.E.2d at 211.

Justice Chapman additionally pointed out that the FDA's regulations contain numerous provisions wholly inconsistent with the notion that "requirement" includes state court decisions. 21 C.F.R. § 808.3(d) defines "political subdivision" as "any lawfully established local governmental unit" that has "the authority to establish or continue in effect any *requirement* . . . ." (Emphasis added.) This definition suggests that courts are not within the class of entities that establish requirements and thus that their decisions are not preempted by § 360k. 642 N.E.2d at 211.

Further, 21 C.F.R. section 808.20(c)(1) provides that a state or political subdivision's application for an FDA exemption from preemption must include:

> Identification and a current copy of any *statute, rule, regulation, or ordinance of the State or political subdivision considered by the State or political subdivision to be a requirement which is preempted, with a reference to the date of enactment, promulgation, or issuance in final form* . . . [and] [i]f the *requirement has been subject to any judicial* or administrative *interpretations*, the State or political subdivision shall furnish copies of such judicial or administrative interpretations.

(Emphasis added.) Nothing in this regulation suggests court decisions are regarded as a source of requirements. 642 N.E.2d at 213. A narrow interpretation of "requirements" tends to support Judge Reinhardt's interpretation of "court decisions" in 21 C.F.R. § 808.1(b) as comprehending "only . . . those court decisions that adopt special rules applicable to medical devices." *Kennedy*, 67 F.3d at 1461 (Reinhardt, J., concurring).

In urging the courts to reconsider and to stop barring claims of persons injured by medical devices, Adler and Mann conclude: "[P]reemption of product liability claims . . . is misplaced—at least without . . . a precise plan for

offsetting approaches to protect consumers. Innovation without protection hardly improves the lives of our citizens and, . . . the FDA by itself simply cannot provide an adequate source of safety to the public from dangerous medical devices." Adler & Mann, *supra*, at 945.

In *Kennedy*, the Ninth Circuit has taken a well-grounded step to assure injured persons an avenue of redress for injuries resulting from medical devices, and we join it. We reverse the judgment below and remand this matter for further proceedings consistent with this opinion.

/s/ Philip E. Toci
PHILIP E. TOCI
Judge

CONCURRING:

/s/ Joe W. Contreras
JOE W. CONTRERAS
Presiding Judge

/s/ Sheldon H. Weisberg
SHELDON H. WEISBERG
Judge

APPENDIX B

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

December 21, 1993

HON. BARBARA M. JARRETT

No. CV 93-02661

ARLENE FIORE, *et vir.*

v.

COLLAGEN CORPORATION, *et al.*

In Chambers. This is the time set for oral argument on Defendant Collagen's Motion For Summary Judgment. Susan A. Allinger is present telephonically on behalf of Plaintiff. John C. Gemmill and Joe W. Redden are present on behalf of Defendant, Collagen. Paul J. Giancola is present on behalf of Defendant Waddington.

Court reporter, Donna Johnson, is present.

The Court hears oral argument on Defendant Collagen's Motion For Summary Judgment.

IT IS ORDERED taking the matter under advisement.

In Chambers recess.

LATER:

Plaintiffs Arlene and Richard Fiore filed a Complaint in this cause raising the following claims: strict tort lia-

bility, negligence, gross negligence, breach of warranty, fraud by Defendant Collagen in obtaining FDA approval to market its Zyderm Collagen Implant, and loss of consortium on the part of Mr. Fiore. The above claims relate to personal injuries Plaintiff Arlene Fiore claims to have sustained when she had an adverse reaction to Defendant's Zyderm Collagen Implant. Defendant Collagen moved for summary judgment on the ground Plaintiffs' claims are preempted by federal law. The Court agrees that all of Plaintiffs' claims are preempted by the Medical Device Amendments to the Food, Drug & Cosmetic Act of 1976 (hereinafter referred to as "MDA"), 21 U.S.C. §§ 360(c), et seq., and the regulations promulgated under that act.

Two Federal Circuit Courts have recently addressed the issue whether plaintiffs may bring state court claims based upon allegations of injury resulting from Collagen injections. Both of those courts have specifically held that such claims are preempted by the MDA, and the regulations promulgated thereunder. *Stamps v. Collagen Corporation*, 984 F.2d 1416 (5th Cir.), *cert. denied*, —— U.S. —— (1993) (holding plaintiff's claims based upon inadequate labeling; failure to warn; and defective design and manufacture preempted by the MDA); *King v. Collegan Corporation*, 983 F.2d 1130 (1st Cir.), *cert. denied*, —— U.S. —— (1993) (holding plaintiff's claims based upon strict liability in tort; breach of express and implied warranties; negligent design, manufacturing and sale; misbranding; misrepresentation; failure to warn; and fraud preempted by the MDA).

Although this Court is not bound by the above federal decisions, the Court finds that they are both well-reasoned and persuasive. As a matter of comity, this Court gives substantial weight to federal decisions construing federal statutes. Further, although Plaintiffs have attempted to distinguish both *Stamps* and *King* from their case, they have failed to provide this Court with any valid authority in support of their contention that both *Stamps* and *King*

were wrongly decided. Accordingly, this Court adopts the construction given the MDA by both the Fifth and the First Circuit, and determines that Plaintiffs' claims are preempted by federal law. Accordingly,

IT IS ORDERED granting Defendant Collagen's Motion for Summary Judgment as to all of the claims asserted by Plaintiffs against Defendant Collagen in this action.

APPENDIX C

SUPREME COURT

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Chief Deputy Clerk

January 17, 1997

RE. ARLENE FIORE/RICHARD FIORE VS. COLLAGEN CORPORATION
Supreme Court No. CV-96-0447-PR
Court of Appeals No. 1 CA-CV 94-0375
Maricopa County No. CV 93-02661

GREETINGS:

The following action was taken by the Supreme Court of the State of Arizona on January 14, 1997, in regard to the above-referenced cause:

ORDERED: Petition for Review—DENIED.

Record returned to Court of Appeals, Division One, Phoenix, this 17th day of January, 1997.

NOEL K. DESSAINT, Clerk

FILED
MAY 9 1997
OFFICE OF THE CLERK

No. 96-1611

In The

Supreme Court of the United States

October Term, 1996

COLLAGEN CORPORATION,

Petitioner,

v.

ARLENE FIORE, et al.,

Respondents.

Petition For Writ Of Certiorari
To The Arizona Court Of Appeals, Division One

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QUESTION PRESENTED

Whether 21 U.S.C. Sec. 360k(a) preempts respondents' state tort law claims against petitioner manufacturer to recover for injuries caused by a PMA-approved Class III medical device.

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STATEMENT OF THE CASE

Respondents Arlene and Richard Fiore respectfully request that this Court deny the petition for writ of certiorari filed by petitioner Collagen Corporation, which seeks review of the Arizona Court of Appeals opinion in this case. The Arizona Court of Appeals opinion is reported at 930 P.2d 477; the order of the Arizona Supreme Court denying petitioner's petition for review was entered on January 14, 1997.

Certain facts set out by Collagen Corporation in its petition are incorrect, misleading and/or incomplete in the following respects.

1. Any assertion by Collagen Corporation that its Class III device Zyderm was approved under the FDA's regulations appearing at 21 C.F.R. Sec. 814.20, et seq., is incorrect. The PMA for Zyderm was approved in 1981 (Pet. 4). C.F.R. regulations for pre-market applications were not promulgated by the FDA until 1986, five years *after* approval of the Zyderm PMA.

2. Petitioner Collagen Corporation's assertion that it cannot modify Zyderm's packaging or warnings without prior FDA approval is false. Petitioner only *partially* cited the FDA's "conditions of approval" for Zyderm, stating that petitioner cannot make any packaging or labeling changes without FDA approval. (Pet. 5). In truth, those portions of the conditions of approval *omitted* by petitioner in its petition unequivocally allow Collagen to make packaging and labeling warning modifications *without* prior FDA approval where such changes would enhance consumer safety, as the FDA's own regulations

provide. *See* 21 C.F.R. 814.39(d)(2)(i)-(iv). Collagen Corporation's hands were not tied in the event it wanted to warn consumers and physicians of autoimmune risks and injuries regarding Zyderm.

3. The FDA had *not* in 1991 "reviewed Zyderm's record and reconfirmed in its initial finding of safety and effectiveness," as alleged by petitioner (Pet. 5). Rather, in response to a congressional investigation involving Collagen Corporation, the FDA re-reviewed the *original* 1980 PMA materials submitted by petitioner for Zyderm, and determined that under 1980 standards, the PMA had been properly approved. Such a finding does not in any way act to rehabilitate what Collagen Corporation has done since 1981, nor absolve Collagen of any fraud claims.

REASONS WHY THE PETITION SHOULD BE DENIED

Petitioner Collagen Corporation seeks review on three grounds, none of which is convincing.

First, petitioner asserts that plenary review should be granted because of an alleged difference in approach taken by the Pennsylvania Supreme Court in *Green v. Dolsky and Collagen Corporation*, 685 A.2d 110 (1996), cert. denied (No. 96-1340, April 14, 1997), and by the Arizona court below. However, as Collagen acknowledges, Collagen sought certiorari in *Green* on this same basis, and this Court has since denied review in *Green*.[1] Indeed, Collagen effectively concedes (Pet. 8) that review should

[1] This Court denied the petition in *Green*, No. 96-1340, on April 14, 1997.

not be granted here in *Fiore* if the petition in *Green* is denied. Thus, plenary review should be denied under Collagen's own assertions.

Second, Collagen asks that the petition be granted, vacated and remanded in light of this Court's decision in *Medtronic v. Lohr*, 518 U.S. ___, 116 S. Ct. 2240 (1996). Collagen argues that, under *Medtronic*, the MDA preempts respondents' tort claims involving Zyderm because it underwent the FDA pre-market approval ("PMA") process. *Medtronic*, however, does not state, or even imply, such a result, and particularly, would not do so in regards to respondent's causes of action, as here shown:

First, the majority opinion in *Medtronic* indicates that a duty-to-warn claim, such as that alleged here by respondents, is not preempted in PMA cases because FDA regulations do not bar manufacturers of PMA devices from providing stronger and different warnings to protect consumer safety. 116 S. Ct. 2256 n. 16. As to respondent's manufacturing-defect claim, the very same federal regulations that were held not to have preemptive effect in *Medtronic* are applicable to the manufacturer of PMA devices, such as the injectable collagen device at issue here. *Medtronic* at 2256-58. *See* 21 C.F.R. Part 820.

Furthermore, regarding respondents' design-defect claims, although the PMA process may be more scientifically "rigorous" (that is, complex) than the 510(k) process, a PMA nonetheless does not require that a device be designed in a particular manner, but only that the manufacturer comply with its own manufacturing specifications set out in the PMA. Thus, the PMA is not a "specific" preemption-triggering requirement, which is a

prerequisite for preemption under *Medtronic*. *Id.* at 2258 (no preemption under the MDA where there is no "specific mandate on manufacturers or producers").

With respect to respondents' claim that petitioner Collagen defrauded the FDA, physicians, and the general public concerning the true characteristics of the device, there is no preemption of such a claim, since it is based on a general state-law duty not to deceive, and not on specific state-law requirements that would interfere with federal regulatory objectives. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992); *Medtronic*, 116 S. Ct. at 2257-58. In any event, *Medtronic* did not address preemption of fraud claims, and therefore provides no basis for remanding this case for further consideration.

Lastly, Collagen seeks a remand on the basis of the Ninth Circuit's decision in *Papike v. Tambrands, Inc.*, 107 F.3d 737 (1997). Although the rationale of *Papike* differed from that of the Ninth Circuit's no-preemption ruling in *Kennedy v. Collagen Corporation*, 67 F.3d 1453, *cert. denied*, 116 S. Ct. 2579 (1996), neither the rationale nor the result of *Papike* bears on the decision below. *Papike* did not even involve a PMA device, but rather a Class II tampon, which is subject to specific, regulatory label warnings mandated by the FDA. The plaintiff in *Papike* alleged that she contracted toxic shock syndrome due to the manufacturer's failure to warn on proper use of the product, arguing that the manufacturer should have given a warning over and above the specific, detailed tampon warnings mandated by the FDA at 21 C.F.R. Sec. 801.430.

Unlike in *Papike*, no specific, mandated federal regulations of that sort are present here, and the PMA

approval process, like the 510(k) process at issue in *Medtronic*, is entirely generic and non-specific. In sum, although *Papike* leaves open a small window in the Ninth Circuit for preemption of damages claims where the FDA has acted by regulation with great specificity, it says nothing about the claims at issue here and thus provides no basis for remand.[2]

Moreover, Collagen Corporation is incorrect in postulating that the holding in *Kennedy* has been modified by *Lohr*. It is true that in *Papike*, the Ninth Circuit retracted its earlier *Kennedy* statement that the MDA cannot preempt state tort claims. Collagen Corporation, however, is erroneously expanding a retraction of the generalized statement into a retraction of the *Kennedy* holding. Nothing in *Papike* or *Lohr* negates the *holding* in *Kennedy* or *Fiore*, which is that the plaintiffs' claims are not preempted by the general PMA process. The Ninth Circuit's application of the MDA preemption did not change in *Papike*, nor was it changed by *Lohr*.

Neither *Lohr* nor *Papike* require or even suggest that the Arizona Court of Appeals decision was wrongly decided. The petition for writ of certiorari should be denied.

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[2] This Court's decision to seek the views of the U.S. Solicitor General in another MDA preemption case, *Iolab v. Hunter*, No. 96-1126 (Order dated April 21, 1997), has no bearing here. *Iolab* involves an investigational device (IDE), not a PMA device. Indeed, as noted above, this Court denied certiorari in a PMA case, *Green v. Dolsky and Collagen Corporation*, No. 96-1340, just a week before seeking the Solicitor General's views in *Iolab*.

CONCLUSION

Respondents Arlene and Richard Fiore respectfully request that writ of certiorari be denied.

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